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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,900	09/18/2003	William F. McKay	4002-3376/PC445.00	8517

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Attn: Noreen Johnson - IP Legal Department
2600 Sofamor Danek Drive
MEMPHIS, TN 38132

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

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01/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/666,900	Applicant(s) MCKAY ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19,27,45-47 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19,27,45-47 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 10/1/09 have been fully considered but they are not persuasive. In response to applicant's argument that Gabbay does not have a string that is "drawn" in the way Applicants use their string, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The claim requires a string through a plurality of sites of a tissue at one end and another end. Since the tissue of Gabbay's implant is folded just as Applicants' tissue material is, the string of Gabbay's device passes through a plurality of sites along a length and is near the other end and secured thereto.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references in their entirety, not selected paragraphs and description. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants argue that the teaching of Lambrecht cannot be said to teach passing a drawstring (same as a guide or control filament) through a multiplicity of sites. First the Examiner would like to again refer Applicants to review Figures 49G, 50F which clearly show that the drawstring passes through a plurality or multiplicity of sites from one end to the other to be able to

Art Unit: 3738

pull on the implant. Additionally, Lambrecht even states that a plurality of sites along the length can be used to secure the drawstring to the implant, paragraphs 207,208,215,216. Applicants are clearly misinterpreting what Lambrecht is illustrating and disclosing. Applicants also argue Lambrecht does not state pulling the implant to cause it to be pleated, but fails to address the fact that the Examiner was rejecting claims as a combination of references not solely one or the other. Clearly Muhanna shows (Fig. 4B) that a pleated configuration can be placed in the nucleus space as seen and admitted by Applicants (page 12 of response 10/1/09). However, what Applicants fail to disclose and enable is how the end is restrained to pull the implant drawstring to cause the pleated configuration to be assumed. Applicants did argue the 112 1st paragraph rejection stating that without undue experimentation one of ordinary skill could perform the step of maintaining the end of the implant stationary by hand but failed to state where this is disclosed. The rejection is maintained. With the teachings of Lambrecht clearly a tissue implant of Muhanna can be pulled with the incorporated drawstring arrangement as taught by Lambrecht to cause the implant to assume the pleated configuration. Applicants argue Lambrecht's arrangement could not cause the implant to assume a pleated configuration. The Examiner would like to know that if a surgeon's hands held the one end of an implant of Lambrecht with the drawstring arranged as seen in Figs. 49G,50F and then pulled the drawstring, what would happen? It is the Examiner's position that this clearly would result in the bunching up to a pleated configuration.

Claim Rejections - 35 USC § 112

Claims 17-19,27,45-47,49,50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pulling a drawstring to cause folding of tissue, does not reasonably provide enablement for the ability to restrain or keep stationary the tissue to cause the folding. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants allege it is understood that a surgeon could hold one end to pull the other. Well that may be true, but the Examiner would like to know how this is possible in a minimally invasive procedure where implants are inserted through small incisions. Thus, how is a surgeon then suppose to hold the end of an implant inserted through a small incision? Second, it is plausible that other means to hold one of the implant are possible, but also not disclosed, such as using forceps or tweezers. Additionally, it is possible to make stationary the end of the implant using staples as is known in the art. However, Applicant never explains how the end of the implant is maintained stationary or really how this is accomplished to thus give one of ordinary skill the necessary understanding the proper use. Thus, the disclosure fails to enable the critical step of how to keep the end stationary such that the pulling of the drawstring can be accomplished.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 51-53,56-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Gabbay (WO 02/39889). Fig. 4 shows an intervertebral disc device having a length of natural tissue **48** with a “drawstring” **50** attached at or near its first end and passes through the tissue at a plurality of sites of at least three. Because the tissue is folded, the string extends through the tissue to or near the second end to keep together the folds and draw together the ends and can be said that it extends beyond the second end such that it can be secured or knotted such that the string does not become removed from the tissue. It has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The string is “adapted to be” pulled. Regarding claim 52, Gabbay discloses natural tissue, page 9, lines 8-13. With respect to claim 53, Gabbay discloses pericardium tissue, page 8, lines 17,18. Regarding claims 57,58, it can be seen that the string passes through at least ten sites on the tissue.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (WO 02/39889) in view of Sybert et al. (2002/107570). Gabbay is explained above. However, Gabbay fails to disclose the natural tissue is SIS or braided construction. Sybert et al. teach that natural tissue (small intestine submucosa) can be

Art Unit: 3738

used to form a prosthetic device, paragraph 31. Sybert additionally teaches that braided construction can be used in tissue implants for providing greater strength, paragraphs 67-70,72. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the natural tissue in Gabbay's spinal implant because of the abundance of SIS and its durability. Additionally it would have been obvious to one of ordinary skill in the art to use braided constructions as taught by Sybert et al. for the implant of Gabbay such that it increases the strength of the prosthesis to better stabilize the spine.

Claims 17,18,27,45-47,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna (6936070) in view of Lambrecht et al. (2002/151979). Muhanna discloses (Fig. 4B) an implant **16** having a length introduced into the disc **21** space. It can be seen that the implanted or second folded configuration has a multiplicity of folds. The Examiner is not giving any special definition to the term "pleated" as it means: a fold of definite, even width made by doubling a material or the like upon itself and pressing or stitching it in place according to dictionary.com. Thus, it can be deduced that the tissue folded over of Muhanna has a pleated configuration. Muhanna also discloses natural tissue, such as pericardium can be used for the material, col. 4, lines 38,50-54. Fig. 3A illustrates the tissue can include a drawstring **15**. However, Muhanna fails to disclose the drawstring passes through the tissue at a multiplicity of sites along the length of the tissue. Lambrecht et al. teach (Fig. 49G) that the drawstring **406** passes through the implant or tissue at a multiplicity of sites.

Lambrecht also teaches the filament aids in manipulating the implant or tissue in the site

Art Unit: 3738

of implantation, paragraph 213. Lambrecht additionally teaches second drawstring can be placed on the implant and thus restrains an end when the user manipulates it and pulls on the other drawstring. As best understood, it would have been obvious to one of ordinary skill in the art to use a multiplicity of sites to secure the drawstring as taught by Lambrecht et al. with the tissue implant inserted in the disc by the method of Muhanna such that it is properly spaced in the disc space entirely to fill the area. Since the site accessed in the patient is minimal or small, the Examiner considers the tissue site or vertebral disc and annulus to aid in holding the tissue essentially in place in addition to the additional drawstring of Lambrecht to maintain stationary an end as the implant is inserted and once it begins to fill the area it causes folding. With respect to claims 45,46, Lambrecht discloses (paragraph 207) the drawstring passes through a multiplicity of sites of the implant of at least 5, see Figs. 49G,50F. Regarding claim 47, Lambrecht fails to explicitly disclose at least ten sites of passing the drawstring through the implant. It would have been an obvious expedient to one of ordinary skill in the art to pass the drawstring through at least 10 sites on the implant since such a modification only involves routine skill in the art and provides predictable results in strengthening the tissue and the ability to manipulate it. Regarding claim 49, Muhanna fails to disclose the tissue is braided. Lambrecht et al. teach (paragraph 209) that the tissue material can be woven (braided). It would have been obvious to one of ordinary skill in the art to use a braided tissue as taught by Lambrecht with the method of Muhanna such that it reinforces or gives a stronger implant material. With respect to claim 50, Muhanna fails to disclose a cannula to deliver the tissue to the disc space. Lambrecht et al. teach the

Art Unit: 3738

use of a cannula to deliver a tissue implant to the disc space, paragraphs 208,210,211. It would have been obvious to one of ordinary skill in the art to use a cannula as taught by Lambrecht et al. with the method of Muhanna to deliver the implant in the disc space and not have it possibly be placed outside the area inadvertently.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna '070 in view of Lambrecht et al. (2002/151979) as applied to claim 27 above, and further in view of Sybert et al. (2002/107570). Muhanna as modified by Lambrecht et al. is explained supra. However, Muhanna in view of Lambrecht fail to teach small intestine submucosa for the tissue implant. Sybert et al. is also explained above. It would have been obvious to one of ordinary skill in the art to use SIS as taught by Sybert et al. with the method of repairing a disc disclosed by Muhanna modified in view of Lambrecht et al. such that it gives the ability to use a versatile tissue that can be easily obtained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hong (5139069) teaches a pleated structure using a drawstring to draw one end of the pleated structure toward the other.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian E Pellegrino/

Primary Examiner, Art Unit 3738